United States
Environmental Protection
Agency

Office of Prevention, Pesticides
and Toxic Substances
(7501C)

PESTICIDE FACT SHEET

Name of Chemical: **Clofencet**
Reason for Issuance: **New Pesticide Registration**
Date Issued: **February 26, 1997**

DESCRIPTION OF CHEMICAL

Generic Name: 2-(4-chlorophenyl)-3-ethyl-2,5-dihydro-5-oxo-4-pyridazinecarboxylic acid, potassium salt expressed as the free acid

Common Name: Clofencet

Trade Names: MON 21200 Technical
MON 21233 Manufacturing Use Product
Genesis® Hybridizing Agent for Wheat

EPA Chemical Code: 128726

Chemical Abstracts Service (CAS) No: 82691-71-0

Year of Initial Registration: 1997

Pesticide Type: Herbicide - Plant Growth Regulator (Hybridizing Agent)

U.S. Producer: Monsanto Company

USE PATTERNS AND FORMULATIONS

Application Sites: Clofencet (Genesis®) is a plant growth regulator for use in the production of hybrid wheat seed. Clofencet is registered for use on wheat as a seed crop and on the rotational crops of the cereal grains group (except rice, wild rice, sweet corn and wheat) and soybeans. This chemical suppresses normal pollen development in female wheat plants without affecting fertility, allowing for cross-pollination by adjacent untreated wheat plants. Because Federal and State regulations prohibit the production of hybrid wheat seed on the same area of land in successive years, the chemical will not be applied to the same field in consecutive years.
Genesis® will not be sold directly to wheat growers and will only be used by specially-trained seed company personnel. It is estimated that at maximum market saturation, Genesis® will be applied to less than 300,000 acres of the total U. S. wheat acreage ($\leq$ 0.5%). Initial use is projected on 12,000 acres or 0.02% of the total U.S. wheat acreage.

Formulation Types: 91.0% solid powder technical
23.1% water soluble concentrate manufacturing-use
22.4% water soluble concentrate end-use (2 lbs. active ingredient/gallon)

Application Types and Methods: Ground application equipment using low-pressure nozzles and low drift flat fan nozzles.

Application Rates: Application rates for wheat between tip emergence of the penultimate leaf (Feekes Scale 7.0, Zadoks Scale 32) and emergence of the flag leaf ligule (Feekes Scale 9.0, Zadoks Scale 39) range from 3 to 50 gallons (3 to 6 lbs. active ingredient) per acre and is applied once per growing season. Reapplication is permitted if rainfall occurs within 24 hours of application but the total of all applications and reapplications must not exceed 10 lbs. active ingredient per acre per season. Application of Genesis® must be made at least 45 days prior to the harvest of the hybrid wheat seed.

Carrier: water; nonionic surfactant; humectant

SCIENCE FINDINGS

Summary Science Statements

Tolerances established for residues of the plant growth regulator, clofencet, [(2-(4-chlorophenyl)-3-ethyl-2,5-dihydro-5-oxo-4-pyridazinecarboxylic acid, potassium salt)] expressed as the free acid in or on the raw agricultural commodities: wheat grain 250 ppm, wheat hay at 40 ppm, wheat straw at 50 ppm and wheat forage 10 ppm; in the animal product commodities of cattle, goats, hogs, horses and sheep: fat at 0.04 ppm, kidney at 10 ppm, meat at 0.15 ppm, meat by-products (except kidney) at 0.5 ppm and milk at 0.02 ppm; in animal product commodities of poultry: eggs at 1 ppm, fat at 0.04 ppm, meat at 0.15 ppm and meat by-products at 0.20 ppm; and rotational crop tolerances in the raw agricultural commodities: soybeans at 30 ppm, soybean hay at 10 ppm and soybean forage at 10 ppm; cereal grains group (except rice, wild rice, sweet corn and wheat): grain at 20 ppm, straw at 4 ppm, forage at 4 ppm, stover (fodder) at 1 ppm and hay at 15 ppm.

Based upon a battery of acute toxicity studies, clofencet technical is classified as Toxicity Category III. The EPA determined a reference dose (RfD) of 0.05 mg/kg/day based on the NOEL of 5.0 mg/kg/day from a chronic (1-year) feeding study in dogs which demonstrated the effect of epididymitis, tubular degeneration and absence of spermatozoa as endpoint effects and using an uncertainty factor (UF) of 100 which was applied to account for both the interspecies extrapolation and the intraspecies variability. Using the Guidelines for Carcinogenic Risk Assessment published September 24, 1986 (51 FR 33992), the EPA has classified clofencet as Group "C" for carcinogenicity (possible human carcinogen) based on the increase in histiocytic sarcomas (malignant) by both pair-wise and trend analyses in female mice. The thyroid C-cell tumors in male rats (mainly benign) were considered to have occurred only at an excessive dose. There were no apparent genotoxicity concerns and little additional support for carcinogenicity based on structure-activity relationship (SAR) with a related wheat hybridizing agent, fenridazon; therefore, the EPA's Carcinogenicity Peer Review Committee recommended that for the purpose of risk characterization, the RfD approach be used for quantitation of human risk.

Using the Dietary Risk Evaluation System (DRES), a routine chronic dietary analysis was based on use of 0.1% of the wheat crop treated, and 0.1% of the cereal grains group (except rice, wild rice, sweet corn and wheat) and soybeans as rotated crops in fields previously containing wheat treated with clofencet. Percent crop treated of 0.1% is based on the registrant's expectations that up to 35,000 acres of wheat grown for seed will be treated in the year 2000. This 35,000 acres is 0.05% of the approximate 70,000,000 acres of wheat which is grown for grain in the U.S. Based on this conservative dietary assessment, the proposed use of clofencet uses 0.73% of the RfD for the U.S. population and for the most highly exposed subgroups, 0.6% for non-nursing infants (<1 year old), 1.6% for children (1-6 years old) and 1.2% for children (7-12) years old. The risk estimate from combined food and

water sources is expected to be below 25% of the RfD even with the addition of a reasonable bounding figure for the contribution from drinking water.

The Federal Food, Drug and Cosmetic Act (FFDCA) section 408, as amended by the Food Quality Protection Act (FQPA) of 1996, provides that the EPA shall apply an additional safety factor of 10 in the case of threshold effects for infants and children to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines, based on reliable data, that a different safety factor would be appropriate. EPA believes that reliable data support using a different safety factor (usually 100X) and not the additional safety factor when EPA has a complete data base and when the severity of the effect in infants or children or the potency or unusual toxic properties of compound do not raise concerns regarding the adequacy of the traditional safety factors. The Agency believes that an additional safety factor for infants and children is not warranted here. First, a complete set of developmental and reproductive studies have been submitted and the EPA has found them to be acceptable. Second, since the NOELs from the developmental and reproductive studies are 7.6X to 200X higher than the NOEL used for the RfD, the Agency does not believe the effects seen in these studies are of such concern to require an additional safety factor. Accordingly, the Agency believes the RfD has an adequate margin of protection for infants and children. The percent of the RfD that will be utilized by the aggregate exposure to clofencet will range from 0.6% for non-nursing infants less than 1 years old to 1.6% for children 1-6 years old. The EPA has concluded that there is reasonable certainty that no harm will occur to infants and children from aggregate exposure to clofencet.

Clofencet was shown to be slightly toxic to practically non-toxic to avian species, practically nontoxic to fish, aquatic invertebrates, estuarine and marine organisms, and honey bees. Environmental hazard precautionary statements are required.
Based on the ecological toxicity and exposure, clofencet will not have an acute or chronic risk to non-target terrestrial and aquatic organisms.

Clofencet is persistent and mobile. As such, it is likely to leach into ground water or reach surface water by runoff if it reaches the soil. In areas where the soils are
highly permeable, the water table is shallow, and sufficient precipitation and/or irrigation occur, the use of clofencet may result in ground water contamination. In areas susceptible to runoff and near water bodies, surface water contamination may occur. However, the overall impact of these properties, especially in relation to ground water quality, may not be as great as expected because of the specialized use. Addition of environmental hazard statements and the restricted use by certified/trained applicators or seed technicians further mitigates risk of any ground or surface water contamination.

<u>Chemical Characteristics</u>

Study	MON 21200 (Clofencet Technical)	MON 21233 (Manufacturing Use)	Genesis® (MON 21250)
Empirical Formula	$C_{13}H_{10}ClN_2O_3$ (free acid)	$C_{13}H_{10}ClN_2O_3$-K	$C_{13}H_{10}ClN_2O_3$-K
Molecular Weight	278.7 (free acid)	316.8 (K salt)	316.8 (K salt)
Color	Fawn	Dark brown	Dark brown
Physical State	Solid powder	Mobile liquid	Mobile liquid
Odor	No obvious odor	No obvious odor	No obvious odor
Melting Point	Melts/decomposes at 269°C	N/A	N/A
Density	1.44 g/ml at 20°C	1.09 g/ml at 20°C	1.12 g/ml at 20°C

Study	MON 21200 (Clofencet Technical)	MON 21233 (Manufacturing Use)	Genesis® (MON 21250)
Solubility	% w:v in distilled water >55.2, pH 5 >65.5, pH 7 >69.6, pH 9 >65.8, methanol = 1.6, acetone <0.05, dichloromethane <0.04, toluene <0.04, ethyl acetate <0.05, n-hexane <0.06	N/A	N/A
Vapor Pressure	$<10^{-7}$ mm Hg at 25°C	N/A	N/A
Dissociation Constant	pKa = 2.83 at 20°C	N/A	N/A
Octanol/Water Partition Coefficient	log K_{ow} = -2.2 at 25°C	N/A	N/A
pH	6.25; 1% aqueous slurry at 25.6°C	8.6 at 21°C	8.0 at 24°C
Stability	Stable at 54°C for 14 days	Stable at 54°C for 14 days	Stable at 54°C after 12 months
Oxidizing or Reducing Action	N/A	Compatible with zinc and a %5 potassium permanganate solution	Compatible with zinc and a %5 potassium permanganate solution
Explodability	N/A	Non-explosive	Non-explosive
Storage Stability	N/A	Stable at 54°C for 14 days	Stable at 54°C after 12 months
Viscosity	N/A	3.1 cps at 25°C	3.39 cps at 25°C
Corrosion Characteristics	N/A	Sedimentation and slight discoloration of polyethylene bottles	Sedimentation and slight discoloration of polyethylene bottles

Toxicology Characteristics

Acute Toxicity - MON 21200 (Clofencet Technical)

Acute Oral Toxicity in Rats: LD_{50} = 3306 mg/kg/day; Toxicity Category III.

Acute Dermal Toxicity in Rats: LD_{50} > 5000 mg/kg/day; Toxicity Category V.

Acute Inhalation Toxicity in Rats: LC_{50} >3.8 mg/l (MON 21233); Toxicity Category IV.

Primary Eye Irritation in Rabbits: moderate irritation; Toxicity Category II.

Primary Dermal Irritation in Rabbits: essentially no irritation; Toxicity Category IV.

Primary Dermal Sensitization in Guinea Pigs: no sensitization; Toxicity Category V.

Subchronic Toxicity

A 90-day neurotoxicity study in rats at doses of 0, 200, 2,000 or 20,000 ppm (males = 0, 12.3, 124.5 or 1,232 mg/kg/day; females = 0, 15.2, 149.8 or 1537.2 mg/kg/day) with a No Observed Effect Level (NOEL) of 20,000 ppm for males and 2,000 ppm for females based on decreased body weight gain in females. At the 20,000 ppm (Highest Dose Tested (HDT)), no neurotoxicity was observed in either male or female rats.

21-day dermal toxicity study in rats at doses of 0, 100, 300 or 1,000 mg/kg/day which showed no significant toxic effects at any dose tested with a systemic and dermal NOEL of 1,000 mg/kg/day.

A 90-day feeding study in dogs at doses of 0, 10, 50, 200 or 500 mg/kg/day with a NOEL of 50 mg/kg/day based on histological findings in the thymus and testes.

A 90-day feeding study in rats at doses of 0, 200, 1,000, 5,000 or 20,000 ppm (males = 0, 12, 60, 311 or 1,207 mg/kg/day; females = 0, 15, 75, 373 or 1,477 mg/kg/day) with a NOEL of 5,000 ppm in the diet based on decreased cumulative weight gain and slightly increased kidney weights in females.

Chronic Toxicity

A 1-year chronic toxicity study in dogs at doses of 0, 5, 30 or 200 mg/kg/day. The NOEL was 5 mg/kg/day based on liver and epididymal/testicular effects.

An 18-month mouse carcinogenicity study at doses of 0, 70, 300, 3,000 or 7,000 ppm (males = 0, 11.45, 50.31, 501.20 or 1,228.22 mg/kg/day; females = 0, 16.92, 70.67, 710.79 or 1,608.46 mg/kg/day) with a systemic NOEL of 3,000 ppm based on decreased survival as well as bone marrow myeloid hyperplasia, lung congestion and skin fibrosis in males and an increased incidence of histiocytic sarcomas in females at 7,000 ppm (HDT).

A 2-year chronic/carcinogenicity study in rats at dietary doses of 0, 100, 1,000, 10,000 or 20,000 ppm (males = 0, 4.7, 47, 470 or 989 mg/kg body weight (bwt)/day; females = 0, 5.9, 58, 607 or 1,288 mg/kg bwt/day) with a systemic NOEL of 1,000 ppm based on hematuria, white/gray lung foci and kidney lesions. Clofencet at 20,000 ppm (HDT) may cause an increase in the number of animals with hepatocellular carcinomas and adenomas/carcinomas in males and an increase in thyroid C-cell adenomas in males and females.

Reproductive Toxicity

A developmental toxicity study in rats at doses of 0, 100, 300 or 1,000 mg/kg/day with a maternal and developmental NOEL of 1,000 mg/kg/day (HDT). There was no developmental toxicity considered to be the result of clofencet administration.

A developmental toxicity study in rabbits at doses of 0, 50, 150 or 500 mg/kg/day) with a maternal and developmental NOEL of 150 mg/kg/day based on mortality, increased abortions and decreased body weight gain, decreased food consumption, lower fetal body weights, increased incidence of fetal hydrocephalus and an increase in the number of fetuses/litters with unossified bones.

A two-generation reproduction study in rats at dietary concentrations of 0, 500, 5,000 or 20,000 ppm (males = 0, 38, 393 or 1,602 mg/kg/day; females = 0, 52, 529 or 2,044 mg/kg/day) with a maternal NOEL of 5,000 ppm based on suggestive increase in mortality, decrease in body weight/weight gains and lung pathology. The reproductive NOEL is 500 ppm based on an increase in pup mortality in F1a and F1b during lactation days 1-4 and decreased body weights during lactation.

Mutagenicity

Acceptable studies on gene mutation and other genotoxic effects: Ames Salmonella Assay; CHO/HGPRT Point Mutation Assay; In Vitro Cytogenetics Assay in Human Lymphocytes; Mouse Micronucleus Assay; and In Vivo/In Vitro Hepatocyte DNA Repair Assay yielded negative results.

Metabolism

A metabolism study in rats indicated that clofencet was rapidly absorbed and excreted by 7 days post-dosing, with the majority of the administered ^{14}C-label (>78%) eliminated in the urine within 24 hours. Analysis of the excreta indicated that ^{14}C-MON 21200 was eliminated mostly unmetabolized in the urine (87.9-92.1% of the administered dose) and in the feces (4.5-9.1% of the administered dose). Less than 1% was of the administered ^{14}C-label was eliminated as expired CO_2. Less than 1% was retained in the tissue at 7 days post-dosing, indicating low bioaccumulation. There were no apparent sex- or dose-related differences in the absorption, distribution, metabolism or elimination.

<u>Environmental Characteristics</u>

Laboratory data suggest that clofencet is persistent and mobile and has a high potential to leach into ground water or reach surface waters by runoff. It is stable to hydrolysis in sterile aqueous pH 5, 7, and 9 buffered solutions. It was moderately persistent to aqueous photolysis, with degradation half-lives increasing with pH. In soil photolysis studies, it was stable, with 74-81% of parent clofencet remaining after 30-32 days. In both photolysis studies, clofencet was stable in dark controls. In an aerobic soil metabolism study, 70% of parent clofencet remained after one year (an extrapolated half-life of approximately 2 to 2.5 years). In an anaerobic aquatic metabolism study, 87% of parent clofencet remained after one year. Batch equilibrium studies suggest that clofencet is very mobile in sand, loamy sand, and silt loam soils. Clofencet is expected to be in the anionic form in most soil environments. Adsorption will be strongly

influenced by pH (greater at low pH values where the free-acid form exists) and the pH-dependent anion exchange capacity of soil colloids, which is typically low at the natural pH of most soils. These factors also suggest that clofencet will be mobile in soils.

Potential to Contaminate Ground Water

On the basis of its high solubility (700,000 ppm) and tendency toward the anionic form in typical soil and water environments, clofencet would be expected to dissolve readily in solution. In areas where the soils are highly permeable, the water table is shallow, and sufficient precipitation and/or irrigation occur, the use of clofencet may result in ground water contamination. However, the overall impact of these properties, especially in relation to ground water quality, may not be as great as expected because of the specialized use (application is under controlled spray conditions only at the flowering stage and to a relatively small acreage). In addition, interception and photodegradation on the foliage as well as reduced volume of water available for leaching due to the transpiration rate of growing wheat plants could substantially reduce the potential ground water impact.

Potential to Contaminate Surface Water

In less-permeable areas more susceptible to runoff and near water bodies, surface water contamination may occur. Clofencet reaching surface waters would likely remain dissolved in the water column. Results of hydrolysis, aquatic photolysis, and aquatic metabolism studies suggest that the chemical would be persistent in surface water.

Ecological Characteristics

Terrestrial

Clofencet is slightly toxic to avian species on an acute oral toxicity basis with an LD_{50} > 2000 mg/kg (duck) and an LD_{50} of 1414 mg/kg (quail) and slightly toxic on a subacute dietary basis with an LC_{50} > 4818 ppm (duck and quail). Avian reproductive studies indicate that clofencet does not affect avian reproduction at ≤ 971 ppm. Clofencet is practically non-toxic to small mammals on an acute oral basis with an LD_{50} = 3,437 mg/kg for male rats and an LD_{50} of 3,150 for female rats. Clofencet is relatively non-toxic to honey bees with an LD_{50} > 100 μg/bee for both contact and oral toxicity.

Seed germination/seedling emergence (Tier II radish: EC_{25} > 1.25 lb ai/A, NOEC = 1.25 lb ai/A; tomato: EC_{25} = 3.1 lb ai/A, NOEL = 1.25 lb ai/A) and vegetative vigor (Tier II tomato: EC_{25} = 5.3 lb ai/A (dry wt.); radish: NOEC = 0.63 lb ai/A (plant ht.)) were adversely affected in a statistically significant manner by clofencet EC_{25} at levels of 3.1 lb ai/A and 5.3 lb ai/A.

The effect of the proposed use of clofencet on wheat on endangered terrestrial species are: birds are unlikely to be affected acutely because the risk quotients (RQs) do not exceed the acute LOC

= 0.1, but they may be affected chronically because the chronic LOC value = 1 was exceeded with corresponding RQ values for short grass, long grass and broadleaf plants/small insects of 2.5, 1.1 and 1.4, respectively. Small mammals may be affected acutely with the acute LOC = 0.1 and RQ values ranging between 0.1 and 0.7 for grass and broadleaf plants/small insects and chronically with the LOC =1 and all chronic RQs ranging between 2.6 - 60. Insects are unlikely to be affected acutely.

Aquatic

Clofencet is practically non-toxic to bluegill sunfish with an LC_{50} > 1073.5 ppb a.i./l and an LC_{50} > 990 ppb a.i./l for rainbow trout. For fresh water invertebrates, clofencet displays low acute toxicity (LC_{50} > 1193 mg/a.i./l) and although chronic toxicity has not been determined, there is sufficient information to characterize clofencet as displaying moderate chronic toxicity. Estuarine/marine invertebrate testing was not required because end-use products containing clofencet are not intended for direct application to the marine/estuarine environment nor is it expected to reach this environment.

Aquatic plant testing was required for clofencet because it has outdoor non-residential terrestrial uses and it is very likely to move off site of application by runoff. The results indicate that the aquatic plants tested have EC_{50} values of > 6.1 ppm.

The effect of the proposed use of clofencet on wheat on endangered aquatic species are: freshwater vertebrates and invertebrates are unlikely to be affected acutely or chronically because none of the RQs exceed the acute (0.05) or chronic (1) LOCs for endangered aquatic organisms. However, semi-aquatic plants may be adversely affected with all plant LOCs having a value of 1 and the RQ being 1.61.

Public Interest Finding

Clofencet (Genesis®), a chemical hybridizing agent (CHA), facilitates the process of making wheat hybrids. Genesis® has advantages over the available means of making hybrid wheat, mainly cytoplasmic male sterility (CMS). More time is required (about 3 years more) to make hybrids by CMS than by using CHAs. In addition, CMS cannot be used with many lines of wheat due to lack of sufficient sterility or poor seed years. No chemical hybridizing agents are currently being used for wheat.

SUMMARY OF REGULATORY POSITION AND RATIONALE

Available data provide adequate information to support the conditional registration of clofencet as a technical product and for MON 21233 Manufacturing Use Product and Genesis® Hybridizing Agent for use on the primary crop wheat, meat and poultry commodities and the rotational crops of soybeans and cereal grains group (except rice, wild rice, sweet corn and wheat).

Labeling Information for MON 21200 Technical and MON 21233 Manufacturing Use Product:

Environmental Hazards Statements

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the Environmental Protection Agency.

Labeling Information for Genesis® (MON 21250) Hybridizing Agent for Wheat:

Environmental Hazards Statements

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

This chemical demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.

This product may not be mixed or loaded within 50 feet of any wells (including abandoned wells and drainage wells), sink holes, perennial or intermittent streams and rivers, and natural or impounded lakes and reservoirs. This setback does not apply to properly capped or plugged abandoned wells and does not apply to impervious pad or properly diked mixing/loading areas.

Operations that involve mixing, loading, rinsing, or washing of this product into or from pesticide handling or application equipment or containers within 50 feet of any well are prohibited unless conducted on an impervious pad constructed to withstand the weight of the heaviest load that may be positioned on or moved across the pad. Such a pad shall be designed and maintained to contain any product spills or equipment leaks, container or equipment rinse or washwater, and rainwater that may fall on the pad. Surface water shall not be allowed to either flow over or from the pad, which means the pad must be self contained. The pad shall be sloped to facilitate material removal. An unroofed pad shall be of sufficient capacity to contain at a minimum 110% of the capacity of the largest pesticide container or application equipment on the pad. A pad that is covered by a roof of sufficient size to completely exclude precipitation from contact with the pad shall have a minimum containment capacity of 100% of the capacity of the largest pesticide container or application equipment on the pad. Containment capacities as described above shall be maintained at all times. The above specified minimum containment capacities do not apply to vehicles when delivering pesticide shipments to the mixing/loading

site. States may have in effect additional requirements regarding wellhead setbacks and operational containment.

Genesis® can contaminate surface water through spray drift.

Under some conditions, Genesis® may also have a high potential for runoff into surface water (primarily via dissolution in runoff water) for several months post-application. These conditions include poorly-draining or wet soils with readily visible slopes toward adjacent surface waters, frequently-flooded areas, areas overlaying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas overlaying tile drainage systems that drain to surface water.

Applications should not be made to a field that is less than 500 feet from large bodies of water.

Do not apply within 50 feet of any surface water body (stream or pond).

Do not apply to sand soils with less than 3% organic matter where the water table depth is less than 30 feet.

When using this compound on coarse-textured (sandy loam or loamy sand) soils, do not apply within 100 feet of any drinking water well that is screened at a depth of 50 feet or less.

Minimum clothing required by the Worker Protection Standard (WPS) for Genesis® Hybridizing Agent includes: long pants, long-sleeved shirt, and shoes plus socks. The restricted entry interval (REI) is 12 hours.

The use of a mechanical transfer system is required to be used by all mixer/loader and/or applicators if more than 50 acres are to be treated in a single day with Genesis® Hybridizing Agent.

SUMMARY OF DATA GAPS

Product Chemistry Data:

1. 61-2 Starting Materials and Manufacturing Process for a full scale production run.

2. 61-3 Discussion of Impurities data for a full scale production run.

Food Quality Protection Act Data for Percent Crop Treated:

3. The registrant must provide annual reports on production of end-use products containing clofencet, number of acres treated, and a best estimate of which crops and how many acres were planted as rotational crops on fields previously planted to wheat treated with clofencet. The registrant must also provide field residue data on wheat grain, forage, hay and straw from commercially treated crops beginning 18 months after the wheat grain is first harvested. Field residue trials on the rotational crops listed in this document may also be required. The Agency will provide for periodic reevaluation of the dietary exposure, if warranted, with percent crop treated, number of acres of wheat treated and end-use product production information must be submitted by the registrant and other available sources, and submitted field residue data. Before expansion beyond 0.1% is allowed, reevaluation of the dietary exposure may be performed using all available information as necessary.

4. The registrant must submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether clofencet share(s) a common mechanism of toxicity with any other substance and, if so, whether any tolerances for clofencet need to be modified or revoked.

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